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PHASE 2 STUDY
DATA SUMMARY REPORT

for
Libby, Montana

Environmental Monitoring for Asbestos

Evaluation of Exposure to Airborne Asbestos Fibers During Routine and Special Activities

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Prepared by
USEPA Region 8
999 18th Street, Suite 500
Denver, CO

with technical assistance from
Syracuse Research Corporation
999 18th Street, Suite 1975
Denver, CO

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1.0 INTRODUCTION

Libby is a community in northwestern Montana located near an open pit vermiculite mine. The mine began limited operations in the 1920's and was operated on a larger scale by the W. R. Grace Company from approximately 1963 to 1990. Studies at the site reveal that the vermiculite from the mine contains amphibole-type asbestos, referred to in this report as Libby Amphibole (LA). Epidemiological studies at the site revealed that workers at the mine had an increased risk of developing asbestos-related lung disease (McDonald et al. 1986, Amandus and Wheeler 1987, Amandus et al. 1987a,b). Although the mine has ceased operations, historic or continuing releases of LA from mine-related materials could be serving as a source of on-going exposure and risk to current and future residents in the area. In support of this, a health study by ATSDR identified a number of individuals in Libby with asbestos-related disease but no known history of occupational exposure (ATSDR 2002a, 2002b).

The U.S. Environmental Protection Agency (USEPA) has implemented several investigations to characterize the nature and extent of LA contamination of the environment in and around Libby. The purpose of this report is to summarize the results of an effort referred to as “Phase 2”. The Phase 2 study was conducted in the fall of 2001 and was designed to address a series of questions related to the sampling and analysis of environmental samples, including the following:

1) What method is best for collection of air samples?

Air samples may be collected using either a stationary monitor (located in a fixed position throughout the sampling event) or a personal air monitor (worn by a human as that person moves about). The potential issue is that, in a location where asbestos fibers are present in a source such as dust, soil, or insulation, some types of human activities may tend to “kick up” asbestos fibers into the air, resulting in an increase in asbestos fiber concentration in the breathing zone of the person engaged in the activity. Thus, while a stationary monitor located in the general vicinity of such an exposure may be useful and appropriate for assessing the "passive" exposures of people who are not engaged in the activity, it may tend to underestimate exposures of the people directly engaged in activities which disturb the source material. ***Therefore, the first objective of Phase 2 was to measure asbestos levels in the breathing zone of individuals engaged in routine and special activities in and about Libby, and to compare those measurements to data collected from co-located stationary air monitors.*** This information is intended to help guide future air sampling activities at the site that are needed to evaluate risks to individuals engaged in both routine and special activities in the home.

2) What method of analysis is best for air samples?

Air samples (filters) may be analyzed for asbestos by several different methods, including Phase Contrast Microscopy (PCM) and Transmission Electron Microscopy (TEM). The PCM method has been used most extensively in the past, and the current EPA slope factor for quantifying lung cancer risk from asbestos in air is expressed in units of risk per PCM fiber per cc of air. However, PCM has some potential limitations, including the inability to distinguish between asbestos and non-asbestos fibers, to distinguish between different mineral classes of asbestos, or to visualize very thin fibers

(<0.25 um). In contrast, TEM can distinguish between asbestos and non-asbestos fibers, can distinguish between asbestos mineral types, and can also identify fibers smaller than those visible by PCM. ***Thus, the second objective of Phase 2 was to analyze a series of different air samples by both the TEM and PCM methods in order to help judge which type of measurement is most appropriate, and to derive a site-specific relationship between the two (if possible)***.

3) Are the levels of asbestos observed in Libby of potential human health concern?

As noted above, the chief reason for collecting data on asbestos fiber levels in air is to support risk assessment and risk management decision-making. ***Thus, the third objective of the Phase 2 study was to utilize the data collected to derive preliminary assessments of the potential health risk to people who engage in the types of routine and special activities investigated during the study.*** It is important to note that, because the Phase 2 study was not intended to be systematic or comprehensive and hence did not span all possible exposure conditions and all exposure locations, the project plan emphasized that the data should be interpreted as providing only an initial estimate of the range of different exposure levels (and hence health risks) that residents of Libby may experience from both routine and special activities.

The data generated from the Phase 2 effort have been utilized in several Risk Memoranda (USEPA 2000, 2001), as well as other site reports and technical memoranda, and have been used to refine sampling and analysis methods in subsequent site investigations at the Libby site. The Phase 2 data are also currently being used to support the Remedial Investigation/Feasibility Study (RI/FS) and the baseline risk assessment (BRA).

Some of the samples collected during the Phase 2 program have been re-analyzed as part of the Supplemental Remedial Investigation Quality Assurance Project Plan (SQAPP) (USEPA 2005), but the results of these re-analyses will be presented elsewhere and are not included in this report.

2.0 PHASE 2 STUDY DESIGN

The Phase 2 Quality Assurance Project Plan (QAPP) (USEPA 2001) provides a detailed description of the Phase 2 study design. Every reasonable effort was made to adhere to the specified study design and methods for sample and data collection. However, as necessary, the study design and collection methods were optimized in the field based on input from the Libby field sample collection teams and with oversight and approval from USEPA. Study design modifications and field sampling deviations were documented using field modification forms. The field modification forms specific to the Phase 2 study are provided in Appendix A.

The following sections provide a brief summary of the purpose and types of data generated during the Phase 2 study.

2.1 Scenarios Evaluated

One of the main objectives of the Phase 2 study was to investigate the concentrations of asbestos fibers in air that may occur in the breathing zone of individuals engaged in a variety of activities that might lead to the disturbance of asbestos-contaminated source materials such as dust, vermiculite insulation, and soil. To this end, Phase 2 was divided into four general activity-based “scenarios”, as follows:

Scenario 1 – Routine Household Activities
Scenario 2 – Active Household Cleaning Activities
Scenario 3 – Active Disturbance of Vermiculite
Scenario 4 – Active Disturbance of Soil (Rototilling Activities)

There were a total of 26 residences in Libby that participated in the Phase 2 study (participation was strictly voluntary). In this report, the residences participating in the Phase 2 study are referenced by a randomly assigned identification code (e.g., Property A, Property B, etc.). Table 2-1 summarizes which residences participated in each scenario, and includes information that was available before Phase 2 began on the occurrence of asbestos contamination in attic insulation, indoor air and indoor dust in these residences.

Scenario 1: Routine Household Activities

Scenario 1 focused on the airborne exposures of residents engaged in routine household activities excluding active cleaning. A total of 16 residences participated in Scenario 1. As seen in Table 2-1, this included residences with and without vermiculite insulation, and residences with and without measured levels of asbestos in indoor air and dust. The types of activities performed during the sample collection period were recorded by the resident in an activity log. Any special activities that were a potential source of increased exposure to airborne asbestos fibers were also recorded in the activity log[1].

[1] At one residence, the field activity log noted that the resident engaged in cleaning activities during the Scenario 1 sample collection period, but the duration and intensity of cleaning was judged to be sufficiently small that any impact on the long-term average exposure was likely to be minimal. Therefore, this sample was retained for inclusion in the Scenario 1 analysis.

Scenario 2: Active Cleaning

Scenario 2 focused on active cleaning-related activities (vacuuming, sweeping, dusting) that are likely to cause increased levels of dust (and hence asbestos) in indoor air. A total of 22 residences participated in Scenario 2 (these residences included 13 of the 16 locations participating in Scenario 1).

In addition to the cleaning activities of vacuuming, sweeping, and dusting, an additional cleaning scenario was evaluated at one residence to assess exposures specifically related to beating sofa cushions. In this report, vacuuming/sweeping/dusting cleaning activities are referred to as Scenario 2A and beating sofa cushions is referred to as Scenario 2B.

Scenario 3: Active Disturbance of Vermiculite

Scenario 3 focused on exposures that occur when vermiculite sources are actively disturbed, such as when a contractor performs remodeling or repair work in a home with vermiculite insulation, or when a resident enters a space (e.g., an attic area) with unenclosed vermiculite insulation. Seven residences participated in Scenario 3. Six of these 7 residences had vermiculite insulation in the attic, and samples of insulation from all six of these attics contained detectable levels of LA when examined by polarized light microscopy (PLM) (see Table 2-1).

Scenario 3 exposure activities were separated into the following categories:

- 3A) Sweeping or moving debris/insulation in attic
- 3B) Cutting holes into ceilings or walls (e.g., replacing a ceiling fan)
- 3C) Replacing or removing carpeting
- 3D) Removing vermiculite via hand-bagging
- 3E) Removing vermiculite via vacuum truck

Scenario 4: Active Disturbance of Soil

Scenario 4 focused on exposures that occur when garden soil is actively disturbed during rototilling activities. This scenario was chosen both because vermiculite is known to have been added to a number of gardens in Libby, and because rototilling is a realistic and aggressive soil-disturbance scenario. While the Phase 2 QAPP specified that rototilling was to be performed for three gardens (1 garden without visible vermiculite and 2 gardens with visible vermiculite), the activity was only completed in one garden (with visible vermiculite). The failure to collect data from three different locations limits the application of the data collected since the range of values between locations and conditions can not be assessed, but does not alter the value of the data at the specific location assessed.

2.2 Collection of Air Monitoring Samples

There were several types of air monitoring samples collected during the Phase 2 study. The sections below summarize the different types of air samples collected and the timing of the sample collection. Table 2-2 summarizes the general air sampling design of the Phase 2 study, and Table 2-3 summarizes the types and number of air field samples collected within each scenario.

Personal Air Monitors

Air monitors worn by an individual engaged in a designated activity are called “personal” air samples. Personal air monitors are worn at the breathing zone (about 4 to 6 feet above ground surface). Two types of personal air samples were collected during the disturbance activity. A “full period” personal air sample was collected from the beginning of the disturbance activity until the end of the disturbance activity. The full period sample represents the average exposure during the disturbance activity. Several “excursion” personal air samples were collected at shorter intervals within the disturbance activity when it was suspected that the highest air concentrations might be present.

Stationary Air Monitors

Air monitors placed in a fixed location are called “stationary” air samples. Stationary air monitors were placed in the main area(s) of the residence where scenario-related activities were occurring. During Scenarios 2 and 3, several outdoor stationary air samples were also collected to monitor for potential releases of contaminated materials during scenario-related activities. For Scenario 4, the stationary air monitors were placed in four locations surrounding the perimeter of the rototilling activity.

Real-time Aerosol Monitors

For Scenarios 2 and 3, HazDust™ real-time aerosol monitors (RAMs) were used to quantify the level of dust particles in indoor air before, during, and after the scenario-related activities. This included both personal and stationary samples. Filters from these RAM monitors were also analyzed for asbestos in the same manner as the personal and stationary filters. For the purposes of this report, all samples obtained from a HazDust™ RAM are designated “HazDust”, while all other samples collected from personal or stationary monitors are identified without this designation.

Collection Timing

For each of the activity-based scenarios, samples that were collected can be categorized into three general time intervals: pre-activity, during activity, and post-activity. In general, the samples of greatest interest are those collected during the activity, since these provide data on the level of LA in air associated with the activity. Stationary samples collected before or after the activity were used mainly to establish a frame of reference for evaluating the sample collected during the activity. Personal air samples collected before and after the various activities were mainly intended for the purposes of ensuring worker protection, and may not be representative of air concentrations likely to be inhaled by residents. Thus, these samples were not evaluated further in this assessment.

2.3 Collection of Source Materials

Each of the four scenarios in Phase 2 was designed to investigate the potential for release of asbestos fibers into air by disturbance of some potential source material (indoor dust, vermiculite insulation, soil). To obtain preliminary information on the relationship between the concentration of asbestos in a source material and the concentration that may result in air when the source is disturbed, samples of indoor dust, vermiculite insulation, and garden soil were collected prior to the commencement of scenario-related activities. Table 2-4 summarizes the source material samples collected for each scenario.

3.0 SAMPLING METHODS

The detailed methods and Standard Operating Procedures (SOPs) used to collect samples of air and potential source media are provided in the Phase 2 QAPP (USEPA 2001). As noted previously, the study design and collection methods were optimized as necessary in the field based on input from the Libby field sample collection teams and with oversight and approval from USEPA. Appendix A provides the field modification forms which document study modifications and deviations. Brief summaries of the sampling methods used in the Phase 2 study are presented below.

3.1 Air

Personal and Stationary Air Monitors

All personal and stationary air samples to be analyzed for asbestos were collected by drawing air through a mixed cellulose ester (MCE) filter in accord with SOP EPA-LIBBY 01 (USEPA 2001). Samples collected using a high-volume pump (primarily the stationary air samples) employed filters that had pores 0.45 um in diameter. Personal air samples were usually collected using a low volume pump and filters with 0.8 um diameter pores. The Phase 2 QAPP (USEPA 2001) specified target volumes for each type of stationary and personal air sample collected to ensure adequate analytical sensitivities. Table 3-1 summarizes the typical volumes achieved for air samples collected during each scenario. As seen, with the exception of Scenario 1 and personal samples from Scenario 2, most air samples achieved the target air volumes. Samples that do not achieve the target volume have decreased sensitivity and may be associated with increased uncertainty in concentration values, but do not otherwise diminish the value of the samples.

Real-time Aerosol Monitors

Airborne dust levels were measured using a real-time aerosol monitor (RAM) in accord SOP EPA-LIBBY-03 (USEPA 2001). Two types of measurements were obtained from the RAMs. First, continuous measurements of airborne dust levels (mg/m^3) were acquired at one-second intervals prior to the activity, during the activity, and at one or more times following the activity. These measures of airborne dust are referred to as RAM dust levels in this report. Second, filters placed within the RAM were analyzed for asbestos in the same manner as personal and stationary filters. These concentrations of asbestos in air derived from RAM filters will be referred to as HazDust asbestos concentrations in this report. Due to the variability in air flow rates through HazDust filters, confidence in estimates of asbestos concentrations in air is low for HazDust samples compared to the asbestos concentrations from stationary and personal air monitors. Because of this, Hazdust asbestos concentrations were only used in an evaluation of the correlation between dust and LA levels in air, and were not used to estimate human exposure or risk.

3.2 Dust

Dust samples were collected on 0.45 um pore MCE filters using a microvacuum method, similar to that detailed in ASTM 5755-95 (ASTM 1995), as modified for this project (USEPA 2001). Dust samples were collected at most of the residences in which routine and active cleaning activities (Scenarios 1 and 2) were investigated. Dust samples were also collected before and after carpet removal activities (Scenario 3C). Surficial dust samples were composite samples collected from two to four different indoor locations (each location area consisting of 100 cm^2). Dust sampling locations included both surfaces (e.g., window sills, shelves) where dust may settle out, as well as floors (e.g., entryways, living areas).

If cleaning activities resulted in the generation of a visible pile of dust or dirt, a sample of this material was also collected using the microvacuum technique. These samples are referred to as "dust pile" samples. Because neither the total area swept nor the total dust mass generated was recorded for these dust pile samples, it is not possible to use the results to calculate either an asbestos loading (s/cm^2) or a concentration (s/g) for these samples. Therefore, samples identified as dust piles were not evaluated in this report.

3.3 Vermiculite Insulation

For several residences participating in the Phase 2 study, vermiculite insulation samples had been collected previously as part of other investigations and additional sample collection was not necessary. If bulk insulation samples were not available for a residence, samples were collected as part of the Phase 2 study. In most instances, the insulation was collected from several locations at different depths in order to obtain a representative sample of the insulation. All insulation samples were collected in accordance with NIOSH Method 9002 (NIOSH 1994b).

3.4 Garden Soil

As part of previous investigations, two surface soil samples had been collected from the garden selected for rototilling. Therefore, no additional soil samples were collected from this area as part of the Phase 2 study.

3.5 Sample Documentation, Handling and Custody Requirement

Data on the type, location, collection method and collection time of all samples were recorded both in a field log book maintained by the field sampling team and on a sample data entry sheet designed to facilitate data entry into the site database (see Section 3.6 below). Hard copies of all field data sheets and field log books generated during the Phase 2 study are stored at CDM field office in Libby and at Volpe (available upon request). All samples collected in the field were maintained under chain of custody during sample handling, preparation, shipment, and analysis.

3.6 Data Management

All information on locations and samples collected, analyses performed, and raw analytical results are stored and maintained in a site database (referred to as the Libby2DB) housed on a SQL server in Research Triangle Park. Raw data for all Phase 2 samples for use in this report were downloaded into a Microsoft Access® database by SRC on January 23, 2006. A copy of the Phase 2 Access database is provided in Appendix B of this report (provided electronically on the attached CD). Any changes made to the Libby2DB since this download will not be reflected in the current Phase 2 Access database.

4.0 SAMPLE PREPARATION AND ANALYSIS METHODS

The detailed analytical methods used to prepare and analyze samples of air, dust, insulation, and soil are provided in the Phase 2 QAPP (USEPA 2001), and are summarized below.

In some instances, problems or errors occurred in the analysis of individual samples, and these are documented in sample-specific laboratory modifications forms prepared by the analytical laboratory. These forms are available from Volpe upon request.

4.1 Air and Dust

Sample Preparation

All air samples collected during this study were prepared for direct examination by PCM in accord with the procedure specified in NIOSH 7400, and samples were prepared for TEM examination in accord with the method specified in ISO 10312. When reliable fiber counts could not be obtained for one or both methods due to excessive particle loading on the filter, an indirect preparation was made and the indirect preparation was re-analyzed by both methods. All dust samples were prepared for PCM and TEM analysis using the indirect preparation method.

Counting Rules

For PCM, the counting rules established by NIOSH 7400 (NIOSH, 1994a) were used for all air samples. Differential counting (i.e., excluding fibers which the analyst suspects are not asbestos) was not employed because, as noted in NIOSH 7400, there is no presently-accepted method for ensuring uniformity of judgment between analytical laboratories.

For TEM, most air and dust samples were analyzed using ISO 10312 (International Organization for Standardization, 1995) counting rules, modified for site-specific purposes to require recording of structures shorter than 0.5 um and also structures with an aspect ratio less than 5:1.

Air clearance samples were analyzed by TEM in accord with the counting rules specified in the Asbestos Hazardous Emergency Response Act of 1986 (the AHERA method). These analyses were performed by the on-site field laboratory in order to shorten the analytical turn-around time. This was necessary since the results from these samples were required to ensure that levels in the home were safe before allowing the residents to return.

Fiber Mineral Classes

When a sample is analyzed by TEM, individual asbestos structures are observed, and their size, shape, and mineral type are recorded. Mineral type was assessed using Selected Area Electron Diffraction (SAED) and Energy Dispersive Spectroscopy (EDS), and each structure was assigned to one of the following four categories:

LA Libby-class amphibole. Structures having an amphibole SAED pattern and an elemental composition similar to the range of fiber types observed in ores from the Libby mine (USGS 2001). This is a sodic tremolitic solid solution series of minerals including actinolite, tremolite, winchite, and richterite, with lower amounts of magnesio-arfedsonite and edenite/ferro-edenite.

OA Other amphibole-type asbestos fibers. Structures having an amphibole SAED pattern and an elemental composition that is not similar to fibers types from the Libby mine. Examples include crocidolite, amosite, and anthophyllite. There is presently no evidence that these fibers are associated with the Libby mine.

C Chrysotile fibers. Structures having a serpentine SAED pattern and an elemental composition characteristic of chrysotile. There is presently no evidence that these fibers are associated with the Libby mine.

NAM Non-asbestos material. These may include non-asbestos mineral fibers such as gypsum, glass, or clay, and may also include various types of organic and synthetic fibers derived from carpets, hair, etc.

4.2 Vermiculite Insulation

Vermiculite insulation samples were evaluated for asbestos content using Polarized Light Microscopy (PLM), in accord with NIOSH 9002. Results (expressed as area percent) were reported either as Non-Detect (asbestos is not present at levels observable by PLM), Trace (asbestos is present but at a level too low [<1%] to be reliably quantified by PLM), or Detect (asbestos is present and a reliable estimate of the area percent [>1%] can be made).

4.3 Garden Soil

As noted previously, no garden soil samples were collected as part of Phase 2 study. However, two soil samples from the rototilled garden had previously been collected and analyzed by PLM in accord with NIOSH 9002. As noted above, PLM results from NIOSH 9002 are reported as either Non-Detect, Trace, or Detect.

5.0 QUALITY CONTROL

A number of Quality Control (QC) samples were collected during this project to help characterize the accuracy and precision of the data obtained. QC samples included both field-based samples (which are submitted blind to the laboratories) and laboratory-based samples.

5.1 Field-Based QC Samples

In the Phase 2 study, two types of field-based QC samples were collected and submitted to the laboratories:

> Field Blank (FB) – This is a filter cassette for either a personal or a stationary air monitor or a microvacuum, but through which no air is drawn. Most field blank samples for air are prepared for analysis using a direct preparation, while field blank samples for dust are prepared using an indirect preparation. As specified in the Phase 2 QAPP (USEPA 2001), the target rate for air and dust field blank collection was 5%. There is no field blank for soil or insulation.

> Field Duplicate (FD) or Field Replicate (FR[2]) – These are repeat samples of environmental medium collected at the same place and at the same time as the primary sample. In the Phase 2 study, only field replicates/duplicates for air and dust were collected. As specified in the Phase 2 QAPP (USEPA 2001), the target rate for field replicates of air was 5%. No target rates were specified for dust, since there are no criteria to judge whether the agreement between samples is within some pre-defined acceptance limit. Duplicate samples of dust were collected only to gain an initial understanding of the degree of inter-sample variability.

Performance Evaluation (PE) standards (samples with known levels of asbestos contamination) were not employed because no suitable certified standards were located for amphibole fibers in air, soil, or insulation at the time of the Phase 2 study.

Results for Field Blanks

Table 5-1 summarizes the analytical results of the PCM and TEM field blanks. As seen, 134 PCM field blank samples and 197 TEM field blank samples[3] were collected as part of the Phase 2 study. Field blanks for PCM and TEM were collected and analyzed at a rate of about 30%. These rates are well above the target rate specified in the Phase 2 QAPP (5%).

For PCM, the average loading across all air field blanks was 0.24 s/mm^2. For TEM, the average loading of LA structures was 0.024 s/mm^2 and 0.28 s/mm^2 for air field blanks and dust field

[2] The Phase 2 Project Plan (USEPA 2001) identified the code for Field Replicate samples as “REP”. The code was changed to “FR” in the Libby 2 Database, which utilizes a two-letter abbreviation.

[3] As noted in Table 5-1, results from one TEM field blank (2-00164) were excluded from this evaluation because it is suspected that this sample was inadvertently an analysis of a field dust sample rather than an authentic field blank. This suspicion is based on the observation that the number of chrysotile structures observed in this sample were similar to counts for two field dust samples collected by the same team at the same property on the same day (N = 16 chrysotile structures), and a second field blank collected at the same time indicates no chrysotile structures were observed. Because only chrysotile structures were observed in this field blank, even if it were retained, it would have no impact on the interpretation of LA loading on field blank filters.

blanks, respectively. A description of how PCM and TEM field blank data were utilized in the interpretation of analytical results for field samples is presented in Section 6.1.

Results for Field Replicates/Duplicates

Field replicates of air were collected at a rate of approximately 3% (12 field replicates / 374 stationary air field samples). While this rate is lower than the target rate (5%) specified in the Phase 2 QAPP, the number of sample pairs (12) is nevertheless adequate to assess the degree of agreement, and this deviation form the QAPP does not significantly impair the assessment of data quality.

A total of 3 duplicate surficial dust samples were collected from locations immediately adjacent to the original dust sampling locations. As noted above, there was no specified number or rate for collection of dust duplicates, and these samples were intended only to provide an initial assessment of variability in dust samples.

Appendix C provides a detailed summary of the TEM and PCM analytical results for each field replicate/duplicate sample, and the results are summarized in Table 5-2. For each pair, the concentration estimates derived from the original and replicate samples were compared using the method for comparison of two Poisson rates described by Nelson (1982).

For air samples analyzed by TEM (upper panel), none of the 12 of the pairs were statistically different. Likewise, for dust analyzed by TEM (middle panel), none of the three pairs were statistically different. For air samples analyzed by PCM (bottom panel), 8 of the 9 pairs were not statistically different from each other, while one pair was significantly different ($p < 0.05$). Figure 5-1 provides a graphical presentation of these PCM data. The dotted line represents the line of identity (the line on which all data would fall if both results were the same). As seen, with the exception of the one data pair, agreement is good between the PCM replicates. The reason for the difference between the original and replicate sample for this one pair is not known, but the overall degree of agreement for air samples is 20/21 (95%), which is consistent with the conclusion that air sample results collected during Phase 2 are reliable.

5.2 Laboratory-Based QC Samples

The following types of QC sample analyses were performed by each of the participating analytical laboratories:

> Recount Same (RS) – This is a TEM grid that is re-examined by the same microscopist who performed the initial examination. The microscopist returns to the same grid openings as were counted in the original examination.
>
> Recount Different (RD) – This is a TEM grid that is re-examined by a different microscopist than who performed the initial examination. The microscopist returns to the same grid openings as were counted in the original examination.
>
> Verified Analysis (VA) – This is a recount of a TEM grid (same grid openings) performed in accord with the protocol for verified analysis as provided in NIST (1994).
>
> Repreparation (RP) – This is a grid that is prepared from a new aliquot of the same field sample as was used to prepare the original grid. Typically this is done within the same

lab as did the original analysis, but a different lab may also prepare grids from a new piece of filter. If the re-preparation is done within a laboratory, the re-preparation and re-analysis should be done by a different person than did the original, whenever possible.

At the time of the Phase 2 QAPP preparation, no quantitative rules had been established for evaluating the results of re-analysis or re-preparation samples. Since then, Libby Laboratory Modification LB-00029a (USEPA 2003) identified program-wide goals for the interpretation of laboratory-based QC samples for TEM re-analyses. The criteria established in LB-00029a are used here to assess the within-laboratory QC samples performed during the Phase 2 investigation.

Appendix D presents the results for each type of laboratory-based QC sample, and the results are summarized below.

Recount (RS, RD, VA) Samples

For recount same (RS), recount different (RD) and verified analyses (VA), comparisons to the original analysis were evaluated on a grid opening-by-grid opening and structure-by-structure basis. Only those grid openings that were able to be re-examined were included in this evaluation. As specified in the LB-00029a, there are three metrics that were evaluated to assess the degree of agreement (concordance) for LA particles between re-analyses:

Total Number of LA Structures – For grid openings with 10 or fewer structures, total LA structure counts must match exactly to be considered concordant. For grid openings with more than 10 LA structures, counts must be within 10% to rank as concordant.

Mineral Class – There must be 100% agreement on mineral type (chrysotile vs. amphibole) to be considered concordant. Within the amphibole assignment, there must be at least 90% agreement on the assignment of LA and OA to be considered concordant.

LA Structure Dimensions – Structure dimension concordance was evaluated for LA structures only. For LA fibers and bundles, structure length and width must be within 0.5 um or 10% (whichever is less stringent) to be ranked as concordant. For LA clusters and matrices, structure length must be within 1 um or 20% (which ever is less stringent) to be ranked as concordant. There are no rules for width concordance for clusters and matrices.

Program-wide assessment of overall concordance rates for recount samples are as follows:

Metric	Program-Wide Assessment		
	Good	Acceptable	Poor
Concordance on LA count	>95%	85-95%	<85%
Concordance on asbestos type	>99%	95%-99%	<95%
Concordance on LA length	>90%	80%-90%	<80%
Concordance on LA width	>90%	80%-90%	<80%

In accord with the Phase 2 QAPP, recounts were performed at a rate of approximately 5% (58 out of 1207). These 58 recounts consisted of 44 RS[4], 3 RD, and 11 VA analyses. In these 58 recounts, a total of 699 grid openings (GOs) were re-analyzed. About 99.6% (694 of 699) of all GOs evaluated were non-detect for LA in both the original analysis and the recount[5]. One or more LA structures were seen in the original and/or recount in only five GOs. The results for these five GOs are summarized in Table 5-3.

As seen, 3 of the 5 GOs were ranked as discordant based on differences in the total number of LA structures. When the same structures were observed, the reanalysis was always in agreement on mineral class assignment and reported width, and was in agreement for 2 of 3 LA structure for reported length. For the one LA structure in which the reported length was ranked as discordant, the length was reported as 9 um in the original analysis and 10.7 um in the reanalysis.

When discrepancies were identified between the original and the recount analyses, the senior analyst for the laboratory determined the basis of the discordance and took appropriate corrective action (e.g., re-training in counting rules, quantification of size, identification of types, etc). Each laboratory maintains records of all cases of discordant results and of actions taken to address any problems.

Because structures were observed in so few grid openings during recounts in the Phase 2 study, it is not possible to draw reliable conclusions about the degree of concordance from these results. Summary statistics for the entire program through the present time are provided in (USEPA, 2006), and these data provide a better basis for drawing conclusions regarding the degree of concordance between recount samples. As noted in footnote 5, the strategy for selecting samples for recounting has also been changed to emphasize samples that have a higher frequency of grids with one or more LA structures, and this will help improve understanding in the degree of concordance as more samples are evaluated in the future.

Re-preparation (RP)

As specified in LB-00029a, re-preparation samples are compared to each other using the method for statistical comparison of two Poisson rates (Nelson 1982). The overall goal is that no more than 5% of all re-preparations yield results that are statistically different.

In the Phase 2 study, re-preparations were performed at a rate of about 2% (19 out of 1207). While this rate is lower than the target rate (5%) specified in the Phase 2 QAPP, the number of re-preparation samples (19) is adequate to draw reliable conclusions about the degree of agreement.

Of the 19 re-preparation samples, 15 were from air samples and 4 were from dust samples. In 17 out of the 19 re-preparation samples, the total number of structures observed in both the

[4] The results from 3 RS analyses were excluded from this evaluation because the grid openings evaluated in the RS analysis were different than those evaluated in the original analysis.
[5] The high frequency of grid opening with no LA structures is a consequence of the fact that samples were selected for recounting before the results of the first analysis were available. Because recounting of grid openings with zero structures present is not very informative, the procedure has subsequently been modified to select samples for re-count after the original result is obtained, which allows for preferential recounting of samples with structures present in one or more grids.

original analysis and the re-preparation was zero[6]. For the two re-preparation analyses in which one or more structures were observed, the original analysis result and the re-preparation result were not statistically different from each other. Thus, overall agreement for re-preparation samples was 19/19 (100%).

5.3 Overall Conclusions Regarding Data Quality

As described in the sections above, the QC samples collected and analyzed as discussed above indicate that the data quality for the samples collected as part of the Phase 2 study is generally good. The evaluation of field blanks show that data collection methods did not introduce contamination. Replicate samples of field air samples showed that results were generally reproducible by both TEM and PCM, and dust field duplicates show that there is limited inter-sample variability between samples collected in close proximity. Re-counting of selected grid openings indicate that some differences may exist between microscopists in the recognition and classification of fibers, but the data are too limited to draw a meaningful conclusion on the magnitude or significance of any inter-analyst variability. Re-preparation and re-analysis of air and dust samples by TEM showed good reproducibility, indicating that differences between grids from the same air or dust filter due to preparation methods are likely to be minor. Based on these QC findings, all data collected during the Phase 2 program are considered to be reliable and appropriate for use without qualification.

[6] Similar to the case for recounting samples discussed above, the procedure for selection of re-preparation samples has been altered to prioritize samples that have detectable levels of LA, and this will help provide more meaningful results in the future.

6.0 DATA REDUCTION

Raw data for all Phase 2 samples are available in Appendix B of this report (provided in a Microsoft Access® database on the attached CD). Methods employed in the calculation of concentration and loading values from these data are summarized below.

Combining Results from Multiple TEM Analyses of a Single Sample

In some instances, the same air or dust sample was analyzed more than one time by TEM. In most cases, the second analysis simply evaluated additional GOs to improve analytical sensitivity for the sample. Therefore, in the Phase 2 study, if an air or dust sample was analyzed more than once by TEM, each analysis result was combined together to represent a single "pooled" result value that collapses across all TEM analyses. As discussed in Technical Memorandum 11 (USEPA 2005), the pooled result was calculated as follows:

$$\text{Pooled Result} = \sum Ni / \sum TAEi$$

where:

Ni = Number of structures for analysis 'i' that meet the specified grouping rules (e.g., PCMEasb, $PCME_{LA}$, Total LA, $BCPS_{LA}$)

TAEi = Total Amount Evaluated for analysis 'i'
For air: TAE (cc) = 1/Air Sensitivity (1/cc)
For dust: TAE (cm^2) = 1/Dust Sensitivity ($1/cm^2$)

Assigning Detect/Non-Detect Status

In order for a field sample to be ranked as a detect, the number of structures counted in the field sample must be higher than the 95th percentile of the range of counts that would be expected to come from background based on field blank results (ASTM D 6620-00). This evaluation is performed as follows:

- Given a mean field blank loading rate of λ_0 (f/mm^2) (see Table 3-1), the mean number of background structures (μ_0) that would be expected during an examination of an area A is:

  $$\mu_0 \text{ (structures)} = \lambda_0 \cdot \text{Total Area (A) of field sample examined } (mm^2)$$

  Note that the value of A (and hence the value of μ_0) can vary from sample to sample.

- Based on μ_0, the Poisson distribution is used to find the number (count) of background structures (*x0*) that would be observed in no more than 5% of a set of random observations of an area A in field blanks.

- If the number of structures (N) counted in the field sample is greater than *x0*, the field sample is ranked as a detect. If N is less than or equal to *x0*, the observed number of structures in the field sample could be attributable to background and the sample is ranked as a non-detect.

Note that for PCM samples, the NIOSH Method 7400 identifies 7 f/mm^2 (5.5 structures in a typical analysis of 100 fields of view) as the cutoff for distinguishing detects from non-detects. However, based on site-specific data (see Table 3-1), the value of λ_0 for PCM is 0.24 s/mm^2, which corresponds to a value of μ_0 of 0.19 structures (assuming analysis of 100 fields of view), which corresponds to a value of 1 for *x0*. Thus, any PCM sample with more than 1 structure was ranked as a detect in this report.

For TEM, site-specific data for air field blanks show that the value of λ_0 for LA by TEM is 0.029 s/mm^2 (see Table 3-1). The value of μ_0 will depend upon the total number of grid openings evaluated and the grid opening size, both of which are analysis-specific. For example, in an analysis of 20 grid openings with a grid opening size of 0.01 mm^2, μ_0 would be equal to 0.006 LA structures, which corresponds to a value of 0 for *x0*. Thus, in this example, if 1 LA structure is observed, the TEM analysis ranks as a detect.

Calculation of Concentration Values for Detects

Once a sample is classified as a detect, the concentration of air concentration or dust loading of asbestos structures is given as:

Air Concentration (f/cc) or Dust Loading (f/cm^2) = N · S

where:

N = Number of structures observed
S = Sensitivity (1/cc for air or 1/cm^2 for dust)

The calculation of the sample sensitivity depends upon the media analyzed (air or dust). For air, the sensitivity is calculated as:

$$S = \frac{A_f}{GO \cdot A_{go} \cdot V \cdot 1000 \cdot F}$$

where:

S = Sensitivity in air (1/cc)
A_f = Effective area of the filter (mm^2)
GO = Number of grid openings examined
A_{go} = Area of a grid opening (mm^2)
V = Volume of air passed through the filter (L)
1000 = Conversion factor (cc/L)
F = Fraction of primary filter deposited on secondary filter (indirect preparation only)

For dust, the sensitivity is calculated as:

$$S = \frac{A_f}{GO \cdot A_{go} \cdot SA \cdot F}$$

where:

S = Sensitivity in dust ($1/cm^2$)
N = Number of structures observed
A_f = Effective area of the filter (mm^2)
GO = Number of grid openings examined
A_{go} = Area of a grid opening (mm^2)
SA = Area vacuumed during sampling (cm^2)
F = Fraction of primary filter deposited on secondary filter

Note that this calculation does not include a correction to account for the potential contribution of structures from background. This is because, in this investigation, the contribution is small (see Table 3-1), and subtraction of an estimated contribution from background could lead to an underestimate of the true concentration in some cases.

Evaluation of Non-Detects in Summary Statistics

USEPA guidance for exposure and risk calculations at Superfund sites recommends that non-detects typically be evaluated by assuming a concentration value equal to ½ the detection limit. However, as described in Technical Memorandum 11 (USEPA, 2005), because the sensitivity (S) reported for an asbestos analysis in is not analogous to a detection limit (LOD), if an asbestos non-detect is assigned a value equal to ½ the analytical sensitivity, the estimate of the mean will be biased high unless the sensitivity is very low and the frequency of non-detects is low. Only when non-detects are evaluated by using a value of zero is the sample mean a reliable estimate of the true mean. Therefore, in this report, when computing summary statistics across a group of samples, all non-detects were evaluated by assuming a value of zero.

Estimating Upper and Lower Confidence Bounds on Individual Samples

The uncertainty around any PCM or TEM estimate of asbestos concentration in a sample is a function of the number of structures observed during the analysis. The 90% confidence interval around any observed number of structures is given by the Poisson distribution:

5% LB = 0.5 · CHIINV[0.95, (2 · N)]
95% UB = 0.5 · CHIINV[0.05, (2 · N+2)]

where:

CHIINV = Inverse chi-squared cumulative distribution function
N = Number of structures observed

As illustrated in Table 6-1, as N increases, the absolute width of the confidence interval increases, but the relative uncertainty [expressed as the 90% confidence interval (CI) divided by the observed value (N)] decreases.

The basic equation for calculation of the upper and lower bounds on the air concentration or dust loading of asbestos structures is given as:

Air Concentration (f/cc) or Dust Loading (f/cm^2) = (LB or UB) · S

where:

LB or UB = Number of structures based on lower bound (LB) or upper bound (UB)
S = Sensitivity (1/cc for air or 1/cm^2 for dust)

Estimating Upper and Lower Confidence Bounds on Summary Statistics

The calculation of confidence bounds across multiple samples is more complicated because both sampling variability (i.e., differences between samples within a location due to random variation) and measurement error contribute to the overall variability. In this report, a screening level approach was used to calculate the LB and UB across multiple samples within the same location. In this approach, the LB on the mean was set equal to the mean of the sample-specific LBs, and the UB on the mean was set equal to the mean of the sample-specific UBs. This simplified approach is likely to overestimate the true confidence bounds.

Sub-Categories of PCME Fibers

When a sample is analyzed by PCM, it is not possible to reliably distinguish between asbestos and non-asbestos particles, or between asbestos particles that are LA and those that are other types of asbestos. However, when samples are analyzed by TEM, it is readily possible to distinguish between asbestos and non-asbestos, and also between LA and other asbestos types. Therefore, for the purposes of comparing PCM results to TEM results, TEM fibers were classified according to the following definitions:

- PCME: This includes all fibers detected by TEM that are equivalent to those that would have been detected using PCM. PCM fibers are equal to or longer than 5um, have an aspect ratio (length:width) of at least 3:1, and are thick enough to be detected by PCM (about 0.25 um in diameter). Note that this will include particles that are not asbestos, as well as all types of asbestos (LA, other amphiboles, chrysotile).

- $PCME_{asb}$: This includes all PCME structures that are asbestos, and excludes all other organic and inorganic particles that are not asbestos.

- $PCME_{LA}$: This includes all PCME structures that are asbestos, and are of the LA type. It excludes any asbestos fibers (chrysotile, other amphiboles) that are not believed to be associated with the Libby mine site.

7.0 RESULTS

Raw data for all Phase 2 samples are available in Appendix B of this report (provided in a Microsoft Access® database on the attached CD). Appendix E includes a summary of the TEM, PCM, and PLM results for all field samples utilized in the Phase 2 study. This appendix is grouped by Scenario (1-4), media type (air personal, air stationary, dust, bulk insulation, soil), sample collection timing (pre/during/post-activity, clearance), and sample type (e.g., HazDust).

7.1 Objective 1: Comparison of Personal vs. Stationary Air Samples

The first objective of the Phase 2 study was to determine if there was a significant difference in the levels of fibers measured in air when the sample was collected in the breathing zone of a person engaged in some activity (personal air samples) compared to a stationary monitor located in the vicinity of the activity.

For the purposes of this evaluation, personal samples were restricted to full period samples (i.e., excursion samples were excluded), because the full period personal samples had collection periods which coincided with the paired stationary samples. If more than one personal or stationary sample was collected from a property (i.e., two individuals participated in the activity or stationary monitors were placed in multiple rooms/floors), the mean air concentration across samples within the same residence was used. Table 7-1 summarizes the by-sample results for all personal and stationary air samples included in this evaluation.

Table 7-2 provides summary statistics for personal and stationary air samples, grouped by analytical method, concentration metric, and activity scenario, as well as information on the ratio of personal vs stationary air values. The ratio between personal and stationary air samples was calculated using two different methods. The first method calculated the ratio for each scenario based on the individual paired data point ratios, and then calculated the mean ratio across all pairs. This method only included pairs for which both samples were detect. The second method calculated the mean concentration of all personal samples and the mean concentration of all stationary samples for each scenario, and then utilized these mean concentrations to estimate the mean ratio.

As seen in Table 7-2, the air concentrations for personal air monitors tend to be higher than air concentrations for stationary air monitors in all scenarios for nearly all concentration metrics (e.g., PCM, $PCME_{asb}$, $PCME_{LA}$,Total LA). In general, ratios between personal and stationary samples tend to be lowest (closer to 1) for Scenario 1 (routine activities) and highest for Scenario 4 (rototilling activities).

Figure 7-1 (TEM $PCME_{LA}$) and Figure 7-2 (PCM) plots the paired data points (i.e., mean personal vs. mean stationary), stratified by activity scenario. Each data point includes bars that show the 90% confidence interval. For reference, each graph also includes a line of identity (the line on which all data would fall if both measures were the same and there were no measurement error). These figures illustrate that paired data points tend to fall below the line of identity, meaning that personal air concentrations tend to be higher than stationary air concentrations. While this difference is seen for both TEM and PCM, it is most apparent for air concentrations analyzed by PCM (Figure 7-2).

Table 7-3 summarizes the results from the statistical comparison of the personal and stationary air concentrations (based on the statistical method in Nelson, 1982). As seen, depending upon the concentration metric evaluated, statistically significant differences between personal and stationary samples were seen at one or more properties for all scenarios. In general, when differences were statistically significant, the personal air concentrations were usually higher than the stationary air concentrations.

This evaluation supports the conclusion that stationary air monitors may tend to underestimate exposure and risk of individuals who engage in activities that disturb asbestos-containing source material. The magnitude of the underestimation depends upon the scenario; scenarios that are associated with routine activities and minimal disturbances (e.g., Scenario 1) are associated with only small differences (ratios close to 1), while scenarios that are associated with active disturbances (e.g., Scenarios 3 and 4) are associated with the greatest differences (ratios above 1). The absolute magnitude of the difference between a pair of stationary and personal samples is expected to be highly variable between different settings, depending on the intensity and duration of disturbance activities, the nature of the source material, the speed and direction of wind or air flow in the vicinity, and the distance between the activity and the stationary monitor.

7.2 Objective 2: Comparison of PCM and TEM Results

The second objective of the Phase 2 study was to analyze a series of different air samples by both the TEM and PCM methods in order to help judge which type of measurement is most reliable and appropriate in determining asbestos levels in air. In particular, the goal was to address two questions related to differences between PCM and TEM:

1) Does PCM overestimate asbestos concentrations relative to TEM, because PCM does not distinguish between asbestos and non-asbestos fibers in a sample?

2) Does PCM underestimate asbestos concentrations relative to TEM, because PCM can not visualize structures thinner than about 0.25 um in thickness?

For the purposes of this evaluation, air samples were restricted to those which had been analyzed by both PCM and TEM. Table 7-4 summarizes the by-sample results for all PCM and TEM analyses included in this evaluation.

The first question was assessed by comparing PCM air concentrations to TEM PCMEasb air concentrations. These results are shown in Figure 7-3. Each data point includes bars that show the 90% confidence interval for each air sample result. For reference, each graph includes a line of identity (the line on which all data would fall if both measures were the same and there were no measurement error). A tabular summary at the bottom of this figure provides summary statistics for air samples from each activity scenario for PCMEasb and PCM.

The ratio between PCMEasb and PCM air samples was calculated using two different methods. The first method calculated the ratio for each scenario based on the individual paired data point ratios, and then calculated the mean ratio across all pairs. This method only included pairs for which both samples were detect. The second method calculated the mean concentration of all TEM samples and the mean concentration of all PCM samples for each scenario, and then utilized these mean concentrations to estimate the mean ratio.

As seen in Figure 7-3, paired data points tend to fall above the line of identity, meaning that PCM air concentrations tend to be higher than PCMEasb air concentrations. In general, PCM air concentrations are between 3-5 times higher than TEM PCMEasb air concentrations. These differences are most apparent in Scenarios 1 (routine activities) and 2 (active cleaning activities). This is probably because samples in a residential setting are likely to contain non-asbestos particles such as carpet fibers, pet hair, etc. These non-asbestos fibers would be counted in the PCM method, but excluded from counts in PCMEasb. In Scenario 3, there is a somewhat clearer (but still weak) correlation between PCMEasb and PCM. Scenario 3 measurements were usually taken in an enclosed work area in which vermiculite insulation was actively disturbed, so it is likely that the majority of particles collected on filters were asbestos, rather than other types of household fibers as in Scenarios 1 and 2.

The second question was evaluated by determining the fraction of all TEM LA structures in air that are longer than 5 um but thinner than 0.25 um. Figure 7-4 presents a summary of the length and width measurements for all LA structures observed in TEM analyses for air samples collected from the Libby site. Structures that are longer than 5 um and thinner than 0.25 um occur in the lower right-hand corner of this figure. As seen, less than 10% of all LA structures longer than 5 um would have been too thin to be counted by PCM. Because this percentage is small, it is concluded that the inability of PCM to detect thin fibers is not likely to be a significant issue at the Libby site, since a majority of LA fibers are 0.25 um or thicker.

This evaluation supports the conclusion that use of PCM will usually tend to overestimate exposure and risk of individuals who engage in activities that disturb asbestos-containing source material, especially in residential environments. Because the relationship between PCM and TEM varies with the setting of the activity, the type of source material, and the location of the air monitor, it is not possible to establish a default site-specific relationship between the two methods.

7.3 Objective 3: Screening Level Estimation of Potential Health Risk

Exceedences of OSHA Standards

The Occupational Safety and Health Administration (OSHA) has established two occupational standards for exposure of workers – an 8-hour time-weighted average (TWA) value of 0.1 PCM fibers/cc, and a short-term exposure limit (STEL) of 1 PCM fibers/cc.

For the purposes of evaluating air samples collected during Phase 2 the STEL was used to evaluate all short-term "excursion" samples (these were generally about 30 minutes in duration), and the OSHA TWA standard was used as a frame of reference for all "full period" samples. It should be noted that some of the "full period" samples did not represent a full 8 hours, but only spanned a time interval of two hours or so. However, that is only because the activity ceased at that time, and the measured concentration values from the full period samples are assumed to be applicable to cases where the activity extended for longer time periods.

As shown in Table 7-5, a number of personal air samples collected during Phase 2 scenario activities exceeded the TWA (upper panel) or the STEL (lower panel), especially for active cleaning (Scenario 2) and active disturbance of vermiculite (Scenario 3) activities. In considering these results, it is important to recognize that occupational exposure standards for asbestos are not generally applicable to (and may not be protective of) residents or workers in non-asbestos environments. This is because occupational standards are intended to protect individuals who a) are fully aware of the hazards of the occupational environment, b) have specific training and access to protective equipment such as respirators and/or protective clothing and, c) actively participate in medical monitoring (USEPA 1995). None of these conditions apply to residents or to workers at typical commercial establishments. Thus, simple compliance with the OSHA standards is not evidence that exposure levels are acceptable in a home or in a non-asbestos workplace. Indeed, levels of concern for residents or workers may occur at exposure levels substantially below the OSHA workplace standards, as discussed below.

Preliminary Cancer Risk Estimates

Risk of cancer (lung cancer, mesothelioma) in humans from inhalation of asbestos fibers is estimated using a mathematical model of the following form:

Risk = Air Concentration (s/cc) · Unit Risk (risk per s/cc)

For the purposes of this evaluation, risk predictions are derived using two alternative risk models, as described below.

<u>IRIS Risk Model</u>

At present, EPA recommends that risks of asbestos be evaluated using the methodology developed in USEPA (1986), and presented on EPA's IRIS web site. In this approach, the concentration of asbestos in air is expressed in terms of PCM (or PCME) structures/cc, where the definition of a PCM(E) structure is any structure that has a length > 5 um, an aspect ratio (length/width) ≥ 3:1, and a thickness ≥ 0.25 um. The unit risk for the IRIS method is 0.23 per PCM(E) s/cc.

One potential limitation to this method is that the PCM analytical method does not distinguish between amphibole and chrysotile structures. However, data have accumulated over the last 10-15 years that suggest amphiboles tend to be more potent that chrysotile, so application of the IRIS model at a site such as Libby where amphiboles are of chief concern might tend to underestimate the true risk.

<u>Berman Crump Risk Model</u>

Because of the potential limitations associated with the IRIS risk model, the EPA has been working to develop an alternative risk model that accounts more precisely for differences in potency between mineral types, and also as a function of particle size. Efforts completed to data are summarized in USEPA (2003). It is important to stress that is approach is still under development and has not undergone agency review or SAB approval. Thus, the results must be viewed as screening-level only. Nevertheless, because the approach attempts to account for differences in potency between amphibole and chrysotile fibers, it does provide an alternative risk estimate that may be useful in estimating the degree of uncertainty in the IRIS risk estimate.

In this approach, the concentration of asbestos in air is based on TEM analysis, counting fibers that are longer than 10 um and thinner than 0.4 um. For convenience, structures that meet these size rules are referred to as "protocol structures" (PS) The lifetime unit risk for exposure of residents to amphiboles of this size category is 6.3 per PS/cc (USEPA 2003).

Adjustments to Account for Less-than Lifetime Exposure

The level of risk associated with any particular exposure scenario depends on the age at start and the age at end of exposure, with risks tending to be higher for exposures that occur early in life compared to exposures that occur later in life. However, for screening purposes, it is possible to adjust the lifetime exposure unit risk to an approximate unit risk for less-than-lifetime exposure as follows:

Unit Risk (less-than-lifetime) = Unit Risk (lifetime) · TWF

where:

TWF = Time-weighting factor (fraction of lifetime exposed). For example, if an activity were performed for 1 hour per day, three days per week for 50 years, the TWF would be:

$$TWF = (1/24) \cdot (3/7) \cdot (50/70) = 0.0128.$$

Plausible screening level exposure frequencies and durations are shown in the top portion of Table 7-6 for both residents and workers (e.g., a local contractor or tradesman that regularly performs repair or reconstruction services at homes in Libby). These values are generally similar to the reasonable maximum exposure (RME) assumptions commonly employed for residents and workers at other Superfund sites, except that the exposure duration was assumed to be somewhat higher than the normal default (25 years for workers and 30 years for residents) due to greater stability of the Libby community.

Estimation of Concentration Values for Use with Risk Models

There are two approaches that can be utilized to calculate the concentration of asbestos in air for use in the risk models described above. For convenience, these are referred to as "risk-based concentrations", to help distinguish them for other measures of concentration that are not intended for use in the risk models.

The first method for computing risk-based concentrations utilizes the raw structure data generated during the TEM analysis to quantify the total number of LA structures observed that meet the dimensional requirements for PCME or PS. The second method utilizes available information on the average fraction of all LA structures observed in air samples from the Libby site that meet the risk-based definitions. The advantage of estimating the concentration of risk-based structures by this approach is increased statistical confidence and decreased cost. For example, at the Libby site, only about 5% of all TEM LA structures are protocol structures. Thus, to get a reliable count of the number of protocol structures in a sample, it would be necessary to count at least 100-200 total LA structures (a slow and costly requirement). Alternatively, if the estimate of concentration is based on Total LA structures, then a reliable estimate can be obtained by counting only 5-10 total LA structures and multiplying by the appropriate "risk-based fraction" (RBF), as follows:

PCME structures = Total LA structures · RBF(PCME)
PS structures = Total LA structures · RBF(protocol structures)

Because of the advantages in statistical confidence and cost savings, this is the approach that EPA has selected for use in assessing risks from various source materials at this site (USEPA, 2003). Details regarding the derivation of these RBF values are provided in Appendix C of USEPA (2005). Based on the most recent download of the LA particle size data from the Libby database (performed on 2/7/2006), the RBF values are as follows:

RBF(PCME) = 0.45
RBF(PS) = 0.055

Results

The middle portion of Table 7-6 presents the mean and maximum air concentrations for each scenario used to assess potential risks from each scenario activity. The screening level risk estimates are shown in the lower portion of Table 7-6 and these values are depicted graphically in Figure 7-5. The results in the upper graph are based on the mean values across samples within each scenario, while the lower graph shows the results for the maximum value within each scenario. Thus, the upper panel yields an overview of the risks that may be "typical" for the scenarios evaluated, while the lower panel reflects the risks at the most contaminated sub-locations.

When exposure is assessed using the IRIS model and concentrations are measured directly by PCM (black diamonds), estimated risks based on the mean exceed the upper bound of USEPA's typical risk range (a value of 1E-04) in all cases except Scenario 4 (rototilling) or low exposure under Scenario 3 (active disturbance based on residential exposure).

When exposure is assessed using the IRIS risk model are concentrations are estimated using TEM $PCME_{LA}$ (grey diamonds), estimated risks based on the mean are lower than 1E-04 for all scenarios except the high exposure under Scenario 3. In all cases, risk estimates based on $PCME_{LA}$ are lower than those estimated based on PCM. As noted above, this is likely because PCM measurements capture a number of structures that are not asbestos, leading to an overestimation of risk. Generally, estimated risks approach or exceed 1E-04 under Scenarios 1, 2, and 3 when based on maximum concentrations.

When risks are evaluated based on the Berman-Crump risk model (white circles), estimated risks are about 3-fold higher than those based on the IRIS model (using $PCME_{LA}$), with risks exceeding EPA's default level of concern (1E-04) for all scenarios except rototilling.

Interpretation of Risk Estimates

In interpreting these risk estimates, it is important to stress that the values are screening level, both because of uncertainties in the concentration term and in the exposure assumptions. Nevertheless, the results indicate that exposure to fibers released to air by disturbance of contaminated source materials may be of human health concern. Further, even though screening level calculations generally tend to be conservative, there are several reasons to think that the risk values above may tend to underestimate risk, as discussed below.

<u>Differences Between Risk Models</u>

As noted above, risk calculations performed using EPA's approved risk methodology (the IRIS method) does not explicitly account for potential differences in potency between chrysotile and amphibole, and hence may tend to underestimate the level of risks at sites such as Libby where exposure is predominantly or exclusively amphibole in nature. Based on the results shown in Table 7-6, an initial estimate of the degree of underestimation is about 3-fold, but this estimate is preliminary and actual differences might be either higher or lower.

Potency of Varying Fiber Sizes

As noted above, because of limitations in the existing data, both the IRIS risk model and the Berman Crump risk model use size bins to assign fiber potencies. That is, the IRIS model assigns toxicity only to structures thicker than 0.25 um and longer than 5 um, and the Berman Crump risk models assigns toxicity only to structures thinner than 0.4um and longer that 10 um in length. However, particles observed at Libby form a continuous distribution (see Figure 7-6), and it seems implausible that fiber potency is truly a step function that drops to zero as the boundary of a bin is crossed. While data are not adequate at present to address this potential limitation, it is an uncertainty that could be associated with an underestimation of risks due to fibers that fall outside of the discrete risk model bins.

Non-Cancer Health Effects

At present, EPA has not developed methods for characterizing or quantifying the risk of non-cancer health effects due to asbestos exposure. In most cases, if a chemical causes both cancer and non-cancer effects, risk of cancer is usually the greatest concern, and if risks are below a level of concern for cancer, they are generally below a level of concern for non-cancer effects. However, in Libby, the rate of asbestosis is 40-60 times the national rate (ATSDR 2000), placing Lincoln County, Montana, among the top ten counties for this condition in the country. Thus, it is possible that non-cancer risks may also be a “risk driver” at this site, and these are not accounted for in the cancer calculations presented above.

Cumulative Risks Across Multiple Pathways

All of the risk calculations presented above focus on the risks from some specified behavior or exposure scenario. However, nearly all residents and workers in Libby are likely to be exposed to LA through a combination of many different pathways. Thus, total risks to an individual, when summed across all relevant pathways, may be substantially greater than indicated in the single-scenario calculations above.

Taken together, these considerations all support the conclusion that risk estimates, derived as above, may underestimate the true public health risk to area residents and workers from on-going exposures to asbestos contamination.

7.4 Relationships Between Sources, Activities, and Exposures

Asbestos fibers that are present in a source material do not pose a health hazard to humans unless the source material is disturbed in a way that asbestos fibers are released to air. Thus, the concentration of fibers in air depends on two main variables: the concentration in the source, and the nature (intensity, duration) of the disturbing force acting on the source. In general, the relationship between the concentration in air and the concentration in a source may be expressed as a “K-factor”, as follows:

C(air) / C(source) = K factor

Although the Phase 2 study did not specifically seek to obtain data that would allow development of robust site-specific K factors, the available data were evaluated to determine if they could provide initial screening level information on likely values and ranges of K factors for varying scenarios. Emphasis was placed on personal rather than stationary air samples, since these are believed to provide the most relevant measure of airborne concentration level for each scenario.

Dust to Air Transfer

The relationship between the concentration of structures in air (s/cc) and the asbestos loading in dust (s/cm^2) may be expressed as a ratio:

Kda (cm^2/cc) = Cair (s/cc) / Ldust (s/cm^2)

The value of Kda is expected to be highly variable, depending on the nature of the forces that disturb the dust and cause the fibers to become resuspended. Thus, it is appropriate to consider that there are a series of Kda values, depending on the forces acting on the dust. Using data collected as part of the Phase 2 study, two basic types of Kda factors can be estimated for a residential setting:

1) The "baseline" value (Scenario 1) that applies under routine household conditions. The forces that lead to dust resuspension include thermal air currents, mechanical vibrations, and “routine” human or pet movements and activities.

2) The "active disturbance" values that apply when dust is being disturbed by an activity such as active cleaning (Scenario 2A), beating cushions (Scenario 2B), or removing carpets (Scenario 3C).

Table 7-7 presents a summary, grouped by property, of all the personal air results for samples collected during Scenario 1 and the dust results for samples collected prior to the commencement of any Scenario 2-related activities. Table 7-8 presents a summary, grouped by property, of all the personal (full period) air results collected during Scenario 2A, 2B, and 3C activities and the dust results for samples collected prior to the commencement of any active disturbance activities. As seen, while asbestos was detected in air or dust at several locations, there was only one case where asbestos was detected in both air and dust for any activity scenario. Because of this, it is not possible to calculate meaningful site-specific Kda values using the limited data available from the Phase 2 study.

Bulk Insulation or Soil to Air Transfer

Bulk insulation or soil can also be a potential source material for asbestos when these bulk materials are disturbed causing a release of asbestos fibers into the air, such as in Scenario 3 (e.g., active disturbance of attic insulation) or Scenario 4 (rototilling garden soil). Table 7-9 presents asbestos levels in bulk insulation and soil as well as the corresponding air concentrations measured during scenario-related disturbances of vermiculite and soil. However, because concentrations in the source material are estimated by PLM and are reported in semi-quantitative bins, it is not possible to compute quantitative transfer factors for releases from these media.

7.5 Correlation Between Airborne Dust and Asbestos

As noted above, real-time aerosol monitors (RAMs) were used to measure the concentration of dust in air during Scenarios 2 and 3, and particles in the air passing through the RAMs was also collected on filters for subsequent evaluation for LA. Figure 7-7 provides an example of the RAM output for dust in air collected during active cleaning activities (Scenario 2A). As seen, observed dust levels varied widely depending upon activity type and location within the residence. For each activity, the mean dust level was calculated by averaging the recorded dust levels across the entire sampling duration.

Figure 7-8 presents a plot of the paired RAM dust levels and corresponding levels of LA in air measured by TEM Total LA on the HazDust filters. Of the 143 filters examined, LA particles were observed in only 11 cases, and the correlation between RAM dust levels and asbestos levels in air is weak (R^2 = 0.14). This weak relationship between airborne dust levels and airborne LA levels is most likely a consequence of the limited analytical sensitivity of most HazDust filter analyses for LA (mean TEM sensitivity = 0.05 cc^{-1}), coupled with a high degree of variability in LA content in dust. Thus, the results should not be interpreted as evidence that disturbance of dust is not a potentially important source of LA in indoor air in Libby.

8.0 CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE INVESTIGATIONS

The data resulting from the Phase 2 study indicate the following main conclusions:

- Analysis of air and dust samples by PCM will generally tend to over-estimate exposure to LA, especially in the residential setting. This is because a number of structures are counted by PCM that are neither asbestos nor LA. Thus, analysis of air and dust samples by TEM, while slower and more costly than PCM, will generally provide more reliable data on actual exposure levels to LA.

- Evaluation of exposure using stationary air samplers will usually tend to underestimate exposure compared to personal air samplers. The magnitude of the underestimation is variable, tending to be smallest for routine exposures, and highest for scenarios that are associated with active disturbances of source materials. Thus, personal air samples are generally preferred. However, it is also important to consider that use of personal air samplers is often inconvenient, and that the analytical sensitivity of personal air samples is often lower than for stationary samplers. Thus, the choice between stationary and personal air sampling for any particular exposure scenario must balance these opposing factors.

- Measured levels of LA in indoor and outdoor air approach or exceed a level of regulatory and/or risk concern at some but not all locations in Libby. In general, the levels of LA in air tend to be highly variable over time and space. This emphasizes the need to collect additional data on the levels of LA that occur in association with a wide range of activities and at a wide range of locations in order to better understand the exposures and risks which may be occurring at the site.

- Concentration values in most samples of air and dust are in a range where TEM analysis based on only 10-20 grid openings is likely to identify only a relatively small number of LA particles. Because there is high analytical uncertainty associated with a small number of detected particles, future sampling efforts should seek to increase the number of grid opening evaluated to the extent allowed by time and cost constraints. This will increase sensitivity and decrease uncertainty in concentration, exposure, and risk estimates.

- The data collected during Phase 2 were not adequate to derive any meaningful estimates of transfer factors for LA from soil to outdoor air, soil to indoor dust, or indoor dust to indoor air. This is mainly because of the high variability in soil, dust, and air values, coupled with a relatively low analytical sensitivity and a resultant high frequency of non-detects for most Phase 2 samples. Future efforts to derive data adequate to estimate transfer factors will require increased analytical sensitivity and an increased numbers of paired samples in order to increase the utility of the data.

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TABLES

FIGURES

APPENDIX A
Field Modification Forms
(provided electronically on the attached CD)

APPENDIX B
Libby Phase 2 Database
(provided electronically on the attached CD)

APPENDIX C
Field Replicate/Duplicate Sample Results

APPENDIX D
Laboratory-Based QC Sample Results

APPENDIX E
Summary of the TEM, PCM, and PLM Phase 2 Field Sample Results